



AMERICAN VETERINARY MEDICAL ASSOCIATION

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October 14, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: New Animal Drug Applications; Sheep as Minor Species (Docket No. 99N-2151)

Dear Sir or Madam:

The American Veterinary Medical Association, on behalf of its 63,000 members, wishes to comment on the proposed rule to reclassify sheep as a minor species for all New Animal Drug Application data collection purposes. The Association is the authorized voice for the profession in presenting its views to government, academia, agriculture, pet owners, the media, and other concerned publics. The objective of the AVMA is to advance the science and art of veterinary medicine, including its relationship to public health, biological science, and agriculture.

The AVMA wholeheartedly supports amendment of the regulations to reclassify sheep as a minor species for all data collection purposes. Veterinarians badly need approved drugs to maintain the health and welfare of U.S. sheep, and the sheep industry needs these products to remain competitive in a global marketplace.

Currently, sheep are classified as a minor species for the purposes of target animal safety and effectiveness studies. However, they are considered a major species for the purpose of determining the human food safety of edible products. The agency proposes the reclassification on the basis of comparative drug metabolism and disposition studies between sheep and other domestic ruminants, predominantly cattle. Further support is offered by the FDA's comparison of products that have been approved for use in both cattle and sheep under current regulations.

We commend the FDA Center for Veterinary Medicine on its science based approach to this matter. Classification of sheep fully as a minor species should lower drug approval research expenses and provide an impetus for sponsors of approved cattle drugs to submit supplemental NADAs for sheep. Most importantly, this incentive may be gained while human food safety is strictly maintained.

Thank you for this opportunity to comment.

Sincerely,

A handwritten signature in dark ink, appearing to read "Bruce W. Little".

Bruce W. Little, DVM
Executive Vice President

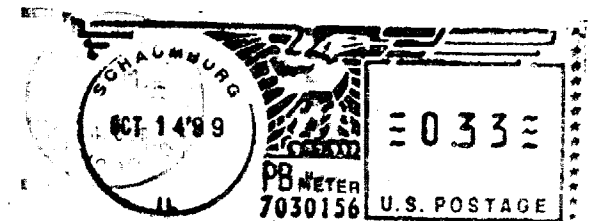
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Scientific Activities

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